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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/659,467
Filing Date: September 10, 2003
Appellant(s): WELSH ET AL.

Heidi S. Nebel
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 21 May 2010 appealing from the Office action mailed 20 August 2008.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-31 are pending. Claim 24 is rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claims 1-4, 24, 25, 30 and 31 are rejected under 35 U.S.C. § 112, first paragraph, for written description.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant's statement concerning the Grounds of Rejection is incorrect. Claims 1-4 were rejected under 35 U.S.C. § 112, first paragraph for Scope of enablement. Claims 24, 25, 30 and 31 were rejected under 35 U.S.C. § 112, first paragraph for Lack of enablement.

Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner:

The rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, for scope of enablement, is withdrawn, based on appellant's arguments.

The rejection of claims 25, 30 and 31, under 35 U.S.C. § 112, first paragraph, for total lack of enablement, is withdrawn, based on appellant's arguments.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

Coryell et al. "Targeting ASIC1a Reduces Innate Fear and Alters Neuronal Activity in the Fear Circuit." Biological Psychiatry, vol 62, no. 10, (Nov 15, 2007), pp. 1140-1148.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim 24, under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Claims 1-4, 24, 25, 30 and 31, under 35 U.S.C. § 112, first paragraph, for written description.

Claim Rejections-35 U.S.C. § 112, First Paragraph - Lack of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 USC 112, 1st paragraph, for total lack of enablement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Appellants are not enabled for a method of treating a disease state *associated with increased pH* by administering an ASIC channel antagonist.

The instant application does not reasonably provide enablement for a method of treating disease states associated with a change in pH by administering an ASIC antagonist without: 1) identifying such diseases, 2) confirming that the diseases embraced by the claim involve a change in pH and 3) that the diseases, furthermore, are related to perturbations of the ASIC receptor. No data are presented in the Specification in which a naturally-occurring disease state is identified and studied as far as the role of pH and as to the involvement of the ASIC channel in the pH change.

The specification gives examples in which ASIC channel function is studied in vitro. Additional experiments demonstrate that ASIC "knockout" mice had certain deficits in learning fear conditioning. However, none of the experiments measured the pH of tissue in which ASIC channels are expressed. No nexus was made between the measured pH of brain regions involved in fear conditioning, the conditioned responses of the animals, and the ASIC channels. Although

experimentation is not required for a method of treatment, neither the instant specification nor the literature hint at a nexus among all three factors of: 1) pH, 2) the ASIC receptor and 3) a disease state.

35 USC § 112, first paragraph - Written Description.

Claims 1-4, 24, 25, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is now based on the fact that appellants were not in possession of an adequate number of compounds that specifically inhibit ASIC to be used in the claimed methods, since only one specific compound has been disclosed and the claims read on any compound that inhibits ASIC.

Claims 1-4, 24, 25, 30 and 31 are directed to methods of treating an anxiety disorder, such as PTSD, by inhibiting ASIC channels. Dependent claims recite pharmaceutical compositions comprising an ASIC receptor antagonist, as well as several routes of administration of the composition. The Specification as filed describes several experiments that confirm the role of the ASIC1a receptor in conditioning and short-term memory. However, the specification does not teach specific ASIC antagonists that can be used for the claimed methods, other than the one example of psalmotoxin (PcTx) provided by Coryell (2007) and that of amiloride, which is a non-specific sodium pump inhibitor.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “appellant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the compound described above, the skilled artisan cannot envision the compounds used for the method of treating PTSD or an anxiety disorder by administering an ASIC antagonist. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the methods claimed. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. The therapeutic products for the claimed methods are themselves required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Appellants have not even disclosed any structural requirements that would be necessary in a genus of ASIC antagonists.

Therefore, only psalmotoxin used for the claimed methods, but not the full breadth of the claims, meet the written description provision of 35 U.S.C. §112, first paragraph. Appellant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

(10) Response to Argument

Claim Rejections-35 U.S.C. § 112, First Paragraph - Lack of Enablement

Claim 24 is rejected under 35 USC 112, 1st paragraph, for total lack of enablement.

The examiner acknowledges that claims 1-4, 25, 30 and 31 are enabled by the instant disclosure when the disclosure is combined with information from Coryell, et al, 2007 (cited above at (8)). Therefore, the examiner will respond only to arguments that are germane to the enablement rejection of claim 24: namely, the contention by appellants that the disclosure is enabling for a method of treating disease associated with increased pH by administering an ASIC antagonist.

Appellants discuss the legal requirements for enablement, with which the examiner generally agrees (Appeal Brief, 21 May 2010, pp. 4-6), and cite the case of the United States v. Teletronics, Inc. (857 F.2d 778, 785, USPQ2d 1217, 1223 (Fed. Cir. 1988), p. 4 and p. 6). Appellants go on to state: "the test to apply is whether one reasonably skilled in the art would be able to make or use the invention based on 'the disclosures in the patent coupled with information known in the art without undue experimentation'" (Appeal Brief, 21 May 2010, p. 4, under Legal Standard for Enablement). Appellant's arguments have been fully considered but they are not persuasive for the following reasons:

U.S. v. Teletronics sets forth the amount of further experimentation needed to enable a claimed invention. The application under review in that case claimed the use of steel electrodes, the use of which surely does not require as much experimentation as the instant claim to a method of treating a disease. Nevertheless, the case has been interpreted to mean that a claimed invention is enabled if any person skilled in the art can make and use the invention without undue experimentation. Such is not the case in the instant application: appellants have made use of a rather weak and non-specific sodium channel antagonist (amiloride) and used it only to block fear conditioning in mice and rats, not to treat diseases associated with an increase in pH.

Furthermore, although appellant's disclosure discussed the high concentrations of ASIC receptors in the amygdala, and pointed to the amygdala as the primary locus of fear-conditioning diseases, such as PTSD, the disclosure however does not discuss the pH of any tissues, including brain tissues - whether diseased or otherwise- nor what a change of pH indicates in terms of treatments for specific diseases that are enabled by the instant specification.

Appellants also argue that "it is unnecessary to 'enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect'" and cite CFMT, Inc. v. Yieldup Int'l Corp., (349 F.3d 1333 (Fed. Cir. 2003)).

Appellant's arguments have been fully considered but are not persuasive for the following reasons. As explained in the MPEP, § 2164: CFMT, Inc. v. Yieldup Int'l Corp describes an invention directed to a general system to improve the cleaning process for semiconductor wafers. The infringement case described the level of improvements necessary to enable the new invention. The result of CFMT, Inc. v. Yieldup Int'l Corp was that the Appellee's invention was enabled by a disclosure showing substantial improvements in the overall system. In addition, the MPEP § 2164 , when discussing CFMT, Inc. v. Yieldup Int'l Corp states: "Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention." And, "a patent claim is invalid if it is not supported by an enabling disclosure." However, in the instant case, the examiner contends that the description of the invention itself is not sufficient to permit those skilled in the art to make and use the invention. For example, no mention is made of pH as it relates to any known diseases, or of diseases that involve a change in pH as well as involving the ASIC channel. Claim 24 specifically requires that the disease being treated is associated with an

increase in pH. Since little instruction was given as to the diseases that involve an increase in pH and that furthermore involve ASIC channels, a method of treating diseases associated with increased pH is not enabled. The fact that acid-sensing channels (ASIC) are antagonized by manipulation of the pH in their environment, as argued by appellants (Brief, 21 May 2010, p. 7, line 18), does not contribute any information to which diseases are associated with an increase in pH, as required by claim 24. Neither does the literature contribute any information regarding diseases associated with an increase in pH.

Appellant's additional discussion under 35 U.S.C. § 112, first paragraph, enablement (pp. 8-12) concerns the scope-of enablement rejection as pertaining to claims 1-4 (withdrawn above); as such, his/her arguments are moot.

Claim Rejections-35 U.S.C. § 112, First Paragraph - Written Description

Claims 1-4, 24, 25, 30 and 31, are rejected under 35 U.S.C. § 112, first paragraph, written description.

The examiner contends that appellants were not in possession of a sufficient number of ASIC antagonists for use in the claimed methods.

Appellants argue that they are "in possession of the various uses for treatment, the variety of ASIC antagonists that could be used or determined by a skilled artisan to make and use, as well as the variety of routes of such treatments, all demonstrating the possession of the claimed invention at the time of filing the present invention" (Appeal Brief, 21 May 2010, p. 13, last paragraph and p. 14, first paragraph).

Appellant's arguments have been fully considered but are not persuasive for the following reasons:

The examiner contends that routes of administration, as well as treatment of several diseases are not written description issues in the instant application. As described in the last Office action (20 August 2009, pp. 7 and 8), the written description rejection only applies to claims 1-4, 24, 25, 30 and 31 because appellants were not in possession of a sufficient number of ASIC-antagonistic compounds. Furthermore, appellant appears to be conflating the enablement requirement with the written description requirement for possession of the compounds. For example, appellant states: "there was possession of the relationship between ASIC and various anxiety and fear responses," (Brief, p. 14) "[t]he specification is enabled for all ASIC antagonists" and: "[t]he claimed invention has sufficient written description for more than the PcTX antagonist alone" (Brief, p. 15, lines 17-19).

However, the written description rejection presented by the examiner applies to the current claims because appellants were in possession of one ASIC channel blocker, that of psalmotoxin (as shown in Coryell, et al, 2008, cited above).

Appellants also discuss the family of ASIC channels, including descriptions of channel domains (Brief, p. 16). However, a discussion of the structure of this family of channels lends very little to a discussion of written description unless it provides information of the types of compounds that would bind ASIC specifically as well as antagonize the channel, which it does not.

Appellants have not demonstrated nor explained exactly how they were in possession of a sufficient number of ASIC antagonist compounds such that the written description rejection may be overcome.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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